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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/002,344 | 10/25/2001 | Herve E. Recipon | DEX-0241 | 4974 |
| 26259 | 7590 | 11/28/2003 | EXAMINER | |
| LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053 | | | HORLICK, KENNETH R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/002,344 | RECIPON ET AL. | |
| | Examiner | Art Unit | |
| | Kenneth R Horlick | 1637 | |

-- **Th. MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/21/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 6, 10-14, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

1. Applicant's election with traverse of Group I, claims 1-5, 7-9, and 15, and SEQ ID NO:81 which encodes SEQ ID NO:221, in the response filed 10/21/03 is acknowledged. The traversal is on the grounds that there is no serious search burden to search all of the groups. This is not found persuasive for the following reasons. First applicants do not address the independence and distinctness of each of the Groups as outlined in the requirement for restriction mailed 09/22/03. Second, the searches are not coextensive as applicants assert. A complete search of the method claims requires more than a search of the sequences, but also includes a search of the methods themselves. Further, there is no right to the search of 10 unrelated sequences in one application.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6, 10-14, 16, 17, and nucleic acid sequences other than SEQ ID NO:81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 10/21/03.

3. The disclosure is objected to because of the following informalities:

(A) A blank appears at page 48, line 27: "yeast_ -mating system".

Appropriate correction is required.

(B) The disclosure contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP j 608.01. Embedded hyperlinks and/or other form of browser-executable code appear in at least the following locations: pages 54, 60, 61, and 129.

4. Claims 1-5, 7-9, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) These claims are vague and indefinite because they claim more than was elected.

B) The recitation of "selectively hybridizes" (claim 1) is vague, indefinite, and incomplete because the term is a relative one and no frame of reference is given. The determination or characterization of selective hybridization requires knowledge or disclosure of other potential hybridization targets and/or probes in the reaction mixture. None is given or mentioned; thus the claim is vague, indefinite, and incomplete.

C) The recitation of "means for determining the presence of the nucleic acid molecule of claim 1" (claim 15) is vague and indefinite because such means are

not clearly defined. While this claim appears to invoke "means plus function" language according to 35 U.S.C. 112, 6th paragraph, it cannot be determined from the specification what means are contemplated. Clarification is required.

5. Claims 1-5, 7-9, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Firstly, this rejection applies to the claims insofar as the embodiments in claim 1 of (c) and (d); that is, nucleic acids which selectively hybridize to SEQ ID NO:81, or those having at least 60% sequence identity to said sequence. Although the specification only discloses the sequence of SEQ ID NO:81, these embodiments cover a large genus of related nucleic acids which are not described and were not in applicant's possession. Included in this genus are any number of nucleic acids which have some sequence homology with SEQ ID NO:81, but nonetheless have substantially different and unpredictable properties, such as encoding a polypeptide of substantially or completely different biological function. Thus, the specification does not have written descriptive support for the large genus as set forth in parts (c) and (d) of claim 1.

Secondly, this rejection applies in another manner with respect to claim 3, which requires genomic DNA. The specification fails to describe the complete genomic DNA

sequence corresponding to the cDNA sequence of SEQ ID NO:81. Thus, applicants were clearly not in possession of the subject matter as claimed in claim 3.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirano et al.

These claims are drawn to an isolated nucleic acid molecule which comprises SEQ ID NO:81, or a nucleic acid that selectively hybridizes to SEQ ID NO:81, or a nucleic acid having at least 60% sequence identity to SEQ ID NO:81.

Hirano et al. teach the cloning of mouse OL-Protocadherin, which has a region of about 88% identity with SEQ ID NO:81 across a portion of about one-third of SEQ ID NO:81 (see pages 995-1005, and also three pages of attached sequence analysis and comparison done by the PTO). The nucleic acid taught by Hirano et al. cannot be distinguished from that being claimed in claim 1, as the OL-Protocadherin sequence (due to the noted region of high homology): i) would be expected to “selectively hybridize” to instant SEQ ID NO:81; and ii) has at least 60% sequence identity to SEQ ID NO:81. The Hirano et al. sequence is a cDNA (claim 2) and is mammalian (claim 4), and this reference further teaches a vector comprising said cDNA, a host cell

comprising said vector, and expression of encoded protein using said host cell (see page 996).

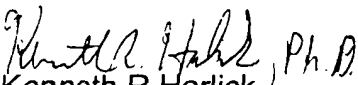
7. It is noted that SEQ ID NO:81 is considered to be patentable subject matter, as no prior art has been found teaching or suggesting this exact sequence. As shown on page 120 of the specification, this sequence was analyzed and found to be "CLASP 2H", wherein expression is only detectable in cancer tissue, and exhibits specificity for lung tumor tissues.

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

11/20/03